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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,222	01/09/2001	Dilip Chokshi	1114-2	6305

23869 7590 09/06/2002

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EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/06/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/757,222	CHOKSHI, DILIP	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 15-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3,4</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1 – 14 in Paper No. 10 is acknowledged.

Claims 15 – 48 are withdrawn from consideration as being drawn to non-elected subject matter.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 – 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising ubiquinone and glycoprotein, as in example 1, does not reasonably provide enablement for a composition of glycoprotein bound to a ubiquinone. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Beyond the product of example 1, applicant has not enabled one in the art to make or use a product which is a glycoprotein bound to ubiquinone. No chemical reaction or steps are detailed which would teach one in the art how to generically bind a glycoprotein to a ubiquinone.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 – 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are rendered vague and indefinite for reciting “bound to” because it is unclear what applicant means by a glycoprotein matrix “bound to” a ubiquinone. The specification does not clearly convey how the glycoprotein is bound as there is no positive recitation of a binding step and the critical elements appear to be missing from the claims. Moreover, applicant’s invention appears to be a composition of a glycoprotein and ubiquinone.

Claim 2 is drawn to a composition however is rendered vague and indefinite for reciting “coQ10” because the term is not first written out, followed by the abbreviation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by McCully (US 5565558).

Applicant claims a composition and a nutritional supplement comprising a glycoprotein matrix and a ubiquinone.

McCully teaches compositions for treating and preventing neoplastic, atherosclerotic, viral and degenerative diseases wherein substances such as ubiquinone, tumor necrosis factor, erythropoietin, colony stimulating factor and granulocyte macrophage stimulating factor are administered (col.6 line 5-28).

The reference anticipates the claimed subject matter.

8. Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yano et al. (US 5298246).

Applicant claims a composition and a nutritional supplement comprising a glycoprotein matrix and a ubiquinone.

Yano teaches compositions comprising ubiquinones and bioactive peptides (glycoproteins) such as erythropoietin, colony stimulating factor, protein C, tumor necrosis factor, lactoferrin, transferrin and immunoglobulins (col.3 line 50 – col.4 line 12).

The reference anticipates the claimed subject matter.

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9. Claims 1 – 2 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Toba et al. (JP 2000281586 A).

Applicant claims a composition and a nutritional supplement comprising a glycoprotein matrix and a ubiquinone. Specifically the ubiquinone is coenzyme Q10.

Toba teaches bone-strengthening compositions comprising lactoferrin (glycoprotein) and vitamin K (ubiquinone or coenzyme Q10) (abstract).

The reference anticipates the claimed subject matter.

10. Claims 1 – 2 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Tomita et al. (US 5804555).

Applicant claims a composition and a nutritional supplement comprising a glycoprotein matrix and a ubiquinone. Specifically the ubiquinone is coenzyme Q10.

Tomita teaches antioxidant compositions comprising lactoferrin hydrosylates (glycoproteins) and coenzyme Q (col.3 line 35-52). The compositions are disclosed to be effective as health-keeping agents, or nutritional supplements (col.8 line 51-64).

The reference anticipates the claimed subject matter.

11. Claims 1 – 5, 8 – 9 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Seuref (GB 2178 662 A).

Applicant claims a composition and a nutritional supplement comprising a glycoprotein matrix and a ubiquinone. Specifically the ubiquinone is coenzyme Q10, in an amount of about 5

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– 15% and with a ratio of glycoprotein matrix to ubiquinone is between about 1:1 to 10:1. The composition further comprises microorganisms, specifically yeast, or *Saccharomyces cerevisiae*.

Seuref teaches compositions of coenzyme Q10 and brewer's yeast (*S. cerevisiae*) (abstract). Specifically, the yeast is disclosed to contain 40% proteins (or glycoproteins). Compositions comprising 5 – 15% Q10 and ratios between 1:1 – 10:1 are disclosed (p.5 line 10-15).

Although Seuref does not teach the Q10 is bound to a glycoprotein, the manner of obtaining the disclosed compositions are the same as that obtained by applicant. As such, it must be inherent to the compositions of Seuref that the ubiquinone and yeast glycoproteins are bound together as claimed by applicant.

Therefore the reference anticipates the claimed subject matter.

12. Claims 1 – 2, 5, 8 – 10 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakao et al. (US 3658648).

Applicant claims a composition and a nutritional supplement comprising a glycoprotein matrix and a ubiquinone. Specifically the ubiquinone is coenzyme Q10 and the composition further comprises microorganisms, yeast, *Saccharomyces cerevisiae* or bacteria.

Nakao teaches compositions of coenzyme Q10 wherein yeasts are fermented to produce coenzyme Q10 (examples, claims). Nakao additionally teaches that ubiquinones are obtainable by incubating bacteria and *S. cerevisiae* (col.1 line 35-48).

Although Nakao does not teach the Q10 is bound to a glycoprotein, the manner of obtaining the disclosed compositions are the same as that obtained by applicant. As such, it must

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be inherent to the compositions of Nakao that the ubiquinone and yeast glycoproteins are bound together as claimed by applicant.

Therefore the reference anticipates the claimed subject matter.

13. Claims 1 – 2, 5 – 7 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Giampapa (US 5895652).

Applicant claims a composition comprising a glycoprotein matrix and a ubiquinone. Specifically the ubiquinone is coenzyme Q10. The composition further comprises microorganisms, specifically yeast, or *Saccaromyces cervisiae*.

Giampapa teaches a nutritional supplement comprising hesperidin, coenzyme Q10, lipase (a glycoprotein) and algae (a microorganism) (col.8 line 38 – col.10 line 3).

The reference anticipates the claimed subject matter.

14. Claims 1 – 2, 5, 8 – 10 and 13 – 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Kurzinger (US 6306453).

Applicant claims a composition comprising a glycoprotein matrix and a ubiquinone. Specifically, the ubiquinone is coenzyme Q10 and the composition further comprises microorganisms. The microorganisms are yeast, specifically *Saccaromyces cervisiae*; bacteria; or yeast and bacteria. Applicant additionally claims a nutritional supplement comprising a ubiquinone bound by a glycoprotein matrix.

Kurzinger teaches compositions comprising vitamins and one or more immuno-stimulators (abstract). Specifically, immuno-stimulators include lactoferrin (glycoprotein),

extracts of bacteria and extracts of *Saccharomyces* (col.2 line 10-23). More specifically, Kurzinger teaches compositions of vitamin K (ubiquinone, coenzyme Q10) and one or more of lactoferrin (glycoprotein), extract of bacteria or extracts of *Saccaromyces cervisiae* (claims).

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1 – 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toba.

Applicant claims a composition and nutritional supplement comprising a glycoprotein matrix and a ubiquinone. Specifically, the ubiquinone is coenzyme Q10 is an amount of about 5 – 15% and the ratio of glycoprotein matrix to ubiquinone is between about 1:1 to 10:1.

Toba teaches bone-strengthening compositions comprising lactoferrin (glycoprotein) and vitamin K (ubiquinone or coenzyme Q10) (abstract).

Toba does not teach the composition comprising 5 – 15% Q10 or the ratio of glycoprotein to Q10 as claimed. However, it would have been obvious to one of ordinary skill in the art to optimize such volumes and ratios since it was routine practice in the art at the time of the claimed invention. Moreover, at the time of the claimed invention, one of ordinary skill in

the art would have been motivated by routine practice to optimize the amounts of Toba with a reasonable expectation for successfully obtaining the bone strengthening composition of Toba.

17. Claims 1 – 5, 8 – 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao.

Applicant claims a composition and a nutritional supplement comprising a glycoprotein matrix and a ubiquinone. Specifically the ubiquinone is coenzyme Q10, in an amount of about 5 – 15% with a ratio of glycoprotein matrix to ubiquinone is between about 1:1 to 10:1. The composition further comprises microorganisms, specifically yeast, *Saccaromyces cervisiae* or bacteria.

Nakao teaches compositions of coenzyme Q10 wherein yeasts are fermented to produce coenzyme Q10 (examples, claims). Nakao additionally teaches that ubiquinones are obtainable from bacteria and *S. cervisiae* (col.1 line 35-48).

Although Nakao does not teach the ubiquinones are bound to a glycoprotein, the manner of obtaining the disclosed compositions are the same as that obtained by applicant. As such, it must be inherent to the compositions of Nakao that the ubiquinone and yeast glycoproteins are bound together as claimed by applicant.

Nakao does not teach the compositions with the claimed amounts of ubiquinone or ratio of ubiquinone to glycoprotein. However, it would have been obvious to one of ordinary skill in the art to optimize such volumes and ratios since it was routine practice in the art at the time of the claimed invention. Moreover, at the time of the claimed invention, one of ordinary skill in

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the art would have been motivated by routine practice to optimize the amounts of Nakao with a reasonable expectation for successfully obtaining the ubiquinone composition of Nakao.

18. Claims 1 – 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa.

Applicant claims a composition and a nutritional supplement comprising a glycoprotein matrix and a ubiquinone. Specifically, the ubiquinone is coenzyme Q10, in an amount of about 5 – 15%, with a ratio of glycoprotein matrix to ubiquinone between about 1:1 to 10:1. The composition further comprises microorganisms and a bioflavonoid, specifically hesperidin.

Giampapa teaches a nutritional supplement comprising hesperidin, coenzyme Q10, lipase (a glycoprotein) and algae (a microorganism) (col.8 line 38 – col.10 line 3).

Giampapa does not teach the composition comprising 5 – 15% Q10 or the ratio of glycoprotein to Q10 as claimed. However, it would have been obvious to one of ordinary skill in the art to optimize such volumes and ratios since it was routine practice in the art at the time of the claimed invention. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts of Giampapa with a reasonable expectation for successfully obtaining a vitamin supplement as disclosed by Giampapa.

19. Claims 1 – 5, 8 – 10 and 13 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurzinger.

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Applicant claims a composition comprising a glycoprotein matrix and a ubiquinone. Specifically, the ubiquinone is coenzyme Q10 is an amount of about 5 – 15% and the ratio of glycoprotein matrix to ubiquinone is between about 1:1 to 10:1. The composition further comprises microorganisms. The microorganisms are yeast, specifically *Saccaromyces cervisiae*; bacteria; or yeast and bacteria. Applicant additionally claims a nutritional supplement comprising a ubiquinone bound by a glycoprotein matrix.

Kurzinger teaches compositions comprising vitamins and one or more immuno-stimulators (abstract). Specifically, immuno-stimulators include lactoferrin (glycoprotein), extracts of bacteria and extracts of *Saccharomyces* (col.2 line 10-23). More specifically, Kurzinger teaches compositions of vitamin K (ubiquinone, coenzyme Q10) and one or more of lactoferrin (glycoprotein), extract of bacteria or extracts of *Saccaromyces cervisiae* (claims).

Kurzinger does not teach the composition comprising 5 – 15% Q10 or the ratio of glycoprotein to Q10 as claimed. However, it would have been obvious to one of ordinary skill in the art to optimize such volumes and ratios since it was routine practice in the art at the time of the claimed invention. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts of Kurzinger with a reasonable expectation for successfully obtaining the immuno-modulating vitamin composition of Kurzinger.

20. Claims 1 – 5 and 10 – 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Metz (Derwent 1998-399777) and Kruzel (Derwent 1991-295636).

Applicant claims a composition and a nutritional supplement comprising a glycoprotein matrix and a ubiquinone. Specifically the ubiquinone is coenzyme Q10, in an amount of about 5 – 15%, or wherein the ratio of glycoprotein matrix to ubiquinone is between about 1:1 to 10:1. The composition further comprises microorganisms, specifically a bacteria, *Lactobacillus*, *Lactobacillus acidophilus* or *Bacterium bifidus*.

Metz teaches a food supplement for aiding the intestines comprising coenzyme Q10 and *Lactobacillus acidophilus* (abstract).

Kruzel teaches nutritional food supplements for preventing microbial infections comprising lactoferrin (a glycoprotein) (abstract).

The references do not teach each of the ingredients together in a single composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their common benefit. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
September 5, 2002



LEON B. LANKFORD, JR.
PRIMARY EXAMINER